IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF LOUISIANA, COMMONWEALTH OF MASSACHUSETTS, STATE OF NEVADA, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF GEORGIA, STATE OF INDIANA, STATE OF MICHIGAN, STATE OF MONTANA, STATE OF NEW HAMPSHIRE, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF NEW JERSEY Ex. Rel. JAMES WETTA

: C.A. No. 04-3479

FILED IN CAMERA AND UNDER

SEAL

JURY TRIAL DEMANDED

VS.

ASTRAZENECA CORPORATION, Wilmington, DE



Qui Tam PLAINTIFFS' MOTION FOR LEAVE TO FILE A FIFTH AMENDED COMPLAINT

Plaintiff James Wetta ("Wetta"), by and through his attorneys, Duane Morris LLP, respectfully moves this Court for an Order granting Plaintiff leave to file his Fifth Amended Complaint attached to the Memorandum of Law in support of this Motion. In support of this Motion, Plaintiff relies upon and incorporates by reference his Memorandum of Law in Support of his Motion for Leave to File a Fifth Amended Complaint.

Respectfully submitted,

DUANE MORRIS LLP Michael M. Mustokoff (Atty. I.D. No. 15674) Teresa N. Cavenagh (Atty. I.D. No. 43845) 30 South 17th Street Philadelphia, PA 19103 (215) 979-1000

SHELLER, P.C. Stephen A. Sheller 1528 Walnut Street, 3rd Floor Philadelphia, PA 19102 (215) 790-7300

FREEDLAND, FARMER, RUSSO BEHREN & SHELLER, PL Gary M. Farmer, Jr., Esquire 7251 West Palmetto Park Road Suite 206 Boca Raton, FL 33343 (561) 416-4848

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF LOUISIANA, COMMONWEALTH OF MASSACHUSETTS, STATE OF NEVADA, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF GEORGIA, STATE OF INDIANA, STATE OF MICHIGAN, STATE OF MONTANA, STATE OF NEW HAMPSHIRE, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF NEW JERSEY Ex. Rel JAMES WETTA

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MICHAELE, KUNZ, Clerk

Qui Tam PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF HIS MOTION FOR LEAVE TO FILE A FIFTH AMENDED COMPLAINT

Plaintiff James Wetta ("Wetta"), by and through his attorneys, Duane Morris LLP, respectfully submits the following Memorandum of Law in Support of his Motion for Leave of Court to File a Fifth Amended Complaint pursuant to Federal Rule of Civil Procedure 15(a). A copy of the proposed Fifth Amended Complaint is attached hereto as Exhibit "1."

I. <u>BACKGROUND</u>

Wetta, a former employee of Defendant AstraZeneca Corporation ("AstraZeneca"), commenced this action on July 22, 2004, by filing a Complaint (the "Complaint") in the Eastern District of Pennsylvania, *in camera* and under seal, against AstraZeneca. Wetta brought this action to recover damages and civil penalties on behalf of the United States of America arising

out of AstraZeneca's conduct in violation of the False Claims Act. 31 U.S.C. § 3729, et. seq. and similar state *qui tam* provisions.

As required under the federal False Claims Act, Wetta provided to the Attorney General of the United States and the United States Attorney for the Eastern District of Pennsylvania, a statement of all material evidence and information related to the Complaint, simultaneously with filing the Complaint.

Wetta alleged in the original Complaint that sometime between January and February 2004, he first learned that AstraZeneca had embarked on a national sales program to aggressively market its drug, Seroquel, to the elderly, children and prisoners in a manner not approved by the Federal Drug Administration ("FDA") through a conspiracy with certain doctors and other health care professionals. Seroquel is a highly sedating, atypical psychotropic drug, most commonly prescribed by psychiatrists and not general medical practitioners. Its FDA approved use is limited to the treatment of schizophrenia and acute bipolar I disorder.

Wetta's Complaint asserted that AstraZeneca's course of conduct constituted a reckless disregard or deliberate ignorance of the truth or falsity of information which it disseminated. AstraZeneca's actions defrauded the United States Government by causing false or fraudulent claims to be presented for payment and to be paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(3) and similar state *qui tam* provisions the Complaint was subsequently amended on September 15, 2004 (the "Amended Complaint"). At the time he filed the Complaint and the Amended Complaint, Wetta was a sales representative in good standing at AstraZeneca.

Subsequent to the his filing of the Amended Complaint, Wetta, uncomfortable and upset with the directions he was receiving from mangers at AstraZeneca to promote the use of

Seroquel to child and adolescent psychiatrists, primary care physicians, and to elderly patients suffering from age related dementia, repeatedly complained to AstraZeneca management about these inappropriate marketing activities. As a result, AstraZeneca began to engage in retaliatory conduct against Wetta, from which he suffered debilitating anxiety and depression and as of December 14, 2005, his employment with AstraZeneca was terminated. Because Wetta's constructive discharge was in violation of Federal and State Retaliation Provisions, on February 15, 2006, Wetta was granted leave to file a Second Amended Complaint to add claims under the potentially applicable retaliation provisions.

On September 7, 2007 Wetta was granted leave to amend file his Third Amended Complaint to include additional claims pursuant to the *qui tam* provisions of Georgia, Indiana, Michigan, Montana, New Hampshire, New Mexico, and New York.

On June 10, 2008, Wetta was granted leave to amend file his Fourth Amended Complaint to include additional claims pursuant to the *qui tam* provision of New Jersey. Wetta now seeks leave to amend his Fourth Amended Complaint to include additional claims pursuant to the *qui tam* provision of Oklahoma, Rhode Island and Wisconsin.

II. <u>ARGUMENT</u>

A. Leave To Amend Should Be Granted Freely

Federal Rule of Civil Procedure 15(a) provides that leave to amend a pleading "shall be freely given when justice so requires." Factors to consider in deciding a motion for leave to amend include undue delay, bad faith, dilatory motive, prejudice, and futility. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3rd Cir. 1997). Recognizing that Rule 15(a) mandates that leave to amend a pleading should be granted freely, the Third Circuit has stated that prejudice to the non-moving party is the most important element in deciding whether to

grant leave to amend. See Cornell & Co. v. Occupational Safety and Health Rev. Comm'n, 573 F.2d 820, 823 (3rd Cir. 1978).

B. No Prejudice Will Result To AstraZeneca Or To The United States Of America if Wetta Is Granted Leave Of Court To File a Second Amended Complaint

No undue prejudice will result to any party if this Court grants the Wetta leave to file a Fifth Amended Complaint. The United States Government will not oppose this motion and, as such, will not be prejudiced if this Court grants the Wetta's Motion. AstraZeneca will not be prejudiced if this Court grants Wetta leave to amend because this litigation is in its earliest stages as it remains under seal and still in its initial evaluation period. Additionally, the addition of the new state *qui tam* claims should not substantially affect the substance of this litigation or cause AstraZeneca to expend greater resources in conducting discovery or preparing a defense. Accordingly, AstraZeneca will not be prejudiced if this Court grants the Wetta's Motion for Leave of Court to File a Fifth Amended Complaint.

III. <u>CONCLUSION</u>

Wherefore, Qui Tam Plaintiff James Wetta respectfully requests that the Court enter the attached order granting leave to file a Fifth Amended Complaint and directing the Clerk's office to docket the proposed Fifth Amended Complaint as filed in camera and under seal as of the day of the Order.

Respectfully submitted,

DUANE MORRIS LLP Michael M. Mustokoff (Atty. I.D. No. 15674) Teresa N. Cavenagh (Atty. I.D. No. 43845) 30 South 17th Street Philadelphia, PA 19103 (215) 979-1000

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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I, Amanda M. Leadbetter, hereby certify that a true and correct copy of the foregoing Motion for Leave to File a Fifth Amended Complaint and its accompanying Memorandum of Law, along with a copy of Plaintiff's proposed Fifth Amended Complaint has been served this _____ day of August, 2008 upon the following:

Laurie Magid, Acting United States Attorney c/o Virginia Gibson, Chief, Civil Division United States Attorney's Office 615 Chestnut Street, Suite 1250 Philadelphia, PA 19106-4476 (Via Hand Delivery)

The Honorable Michael B. Mukasey Attorney General United States Department of Justice 950 Pennsylvania Avenue, N.W. Washington, DC 20430-0001 (Via Certified Mail)

Amanda M. Leadbetter, Esquire

FILED

AUG 1 - 2008

MICHAEL E. KUNZ, Clerk Dep. Clerk

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF

DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF HAWAII,

STATE OF ILLINOIS, STATE OF

LOUISIANA, COMMONWEALTH OF MASSACHUSETTS, STATE OF NEVADA, STATE OF TENNESSEE, STATE OF TEXAS,

COMMONWEALTH OF VIRGINIA, STATE OF GEORGIA, STATE OF INDIANA, STATE OF MICHIGAN, STATE OF MONTANA,

STATE OF NEW HAMPSHIRE, STATE OF NEW MEXICO, STATE OF NEW YORK,

STATE OF CALIFORNIA, STATE OF NEW JERSEY, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF

WISCONSIN, Ex. Rel, JAMES WETTA

vs.

ASTRAZENECA CORPORATION, Wilmington, DE

: C.A. No. 04-cv-3479

: FILED IN CAMERA AND UNDER SEAL

JURY TRIAL DEMANDED

AUG 5 2808 HALLE, KUNZ, Clerk Dep. Clerk

FIFTH AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

I. JURISDICTION AND VENUE

- 1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from Defendant AstraZeneca Inc. Corporation's ("AstraZeneca") conduct in conspiring to have caused false claims to be presented under the federal Medicare, Medicaid and CHAMPUS programs.
- 2. Medicare is a federally funded health insurance program primarily for the elderly.

 Medicaid is a state and federal assistance program to provide payment of medical expenses for low income patients. The Civilian Health and Medical Program of the Uniform Services

("CHAMPUS") is a program of medical insurance benefits provided by the federal government to individuals with family affiliations to the military services.

- 3. This *Qui Tam* claim arises under the provisions of the federal False Claims Act, 31 U.S.C. §3729, et seq. and those False Claims statutes of the twelve captioned states. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 31 U.S.C. §3732 which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.
- 4. Personal jurisdiction and venue for this action are predicated on 31 U.S.C. §3732(a) which provides that "any action brought under §3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business or in which any act prescribed by §3729 occurred". Defendant AstraZeneca transacts substantial business in the Eastern District of Pennsylvania.
- 5. This Court also has supplemental jurisdiction over the California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee, Texas, Virginia, Georgia, Indiana, Michigan, Montana, New Hampshire, New Mexico, New York, New Jersey, Oklahoma, Rhode Island and Wisconsin *Qui Tam* claims pursuant to 28 U.S.C. §1367 which provides that "in any civil action of which the district courts have original jurisdiction, the district court shall have supplemental jurisdiction over all claims that are so related to claims in action in such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution".
- 6. Under the False Claims Act, this Fourth Amended Complaint is to be filed *In*Camera, remain under seal for a period of at least sixty (60) days and shall not be served on the

 Defendant until the Court so orders. The government may elect to intervene and proceed with

the action within sixty (60) days after it receives both the Complaint and the material evidence and information.

7. As required under the False Claims Act, Relators have provided to the Attorney General of the United States and the United States Attorney for the Eastern District of Pennsylvania simultaneously with the filing of this Complaint, a statement of all material evidence and information related to the Complaint. This disclosure statement supports the existence of false claims by AstraZeneca in the Medicare, Medicaid and CHAMPUS programs.

II. PARTIES

- 8. Qui Tam Plaintiff, James Wetta, is a citizen and resident of the state of California. He brings this action on behalf of the United States of America and residents of the captioned states.
- 9. James Wetta is a former employee of AstraZeneca, who worked as a sales representative. He has personal knowledge of AstraZeneca's conduct and its conspiracy with certain doctors, as set forth herein.
- 10. As required under the False Claims Act, James Wetta has provided to the Attorney General of the United States and the United States Attorney for the Eastern District of Pennsylvania simultaneously with the filing of this Complaint, a Statement of All Material Evidence and Information related to the Complaint. This disclosure statement supports the existence of false claims made by AstraZeneca and possibly others to the Medicare, Medicaid and CHAMPUS programs. AstraZeneca's principal place of business is Wilmington, Delaware.

III. ALLEGATIONS

11. Sometime between January and February 2004, Relator, James Wetta, first learned that AstraZeneca had embarked on a national sales program to aggressively market its drug, Seroquel, to the elderly, children and prisoners in a manner not approved by the Federal Drug Administration ("FDA") through a conspiracy with certain doctors and other health care

professionals. Seroquel is a highly sedating, atypical psychotropic drug, most commonly prescribed by psychiatrists and not general medical practitioners. Its FDA approved use is limited to the treatment of schizophrenia and acute bipolar I disorder.

- 12. AstraZeneca has, through the use of its own sales force and a group of highly compensated outside physicians, promoted Seroquel to elderly patients, children and prisoners.

 Many of these patients suffer from a wide spectrum of psychiatric mood and other disorders not normally considered by the FDA to be appropriate for treatment with Seroquel.
- 13. The FDA package insert for Seroquel is clear in the limited indications for the drug. Seroquel is indicated for the short-term treatment of schizophrenia and the short term treatment of acute manic episodes associated with schizophrenia and bipolar disorder as either monotherapy or adjunctive therapy to Lithium or Divalproex.

14. The package insert states that:

The efficiency of Seroquel was established in two three-week monotherapy trials and one three-week adjunct therapy trial of bipolar I patients initially hospitalized for up to seven days for acute mania. Effectiveness for more than three weeks has not been systematically evaluated in clinical trials. Therefore, the physician who elects to use Seroquel for extended periods should periodically re-evaluate the long term risks and benefits of the drug for the individual patients. Schizophrenia . . . The efficiency of Seroquel in schizophrenia was established in short-term (six weeks) controlled trials of schizophrenic patients. The effectiveness in long-term use, that is more than six weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Seroquel for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patients.

15. Despite those limitations in FDA approved indications, AstraZeneca is aggressively marketing Seroquel as a long term cure-all for a broad spectrum of psychiatric maladies including, but not limited to: 1) anger management; 2) dementia; 3) post-traumatic stress; 4)

mood disorders; 5) refractory depression; 6) Parkinson's disease; and 7) cognitive dysfunction, hostility, aggression and agitation in children.

- 16. Seroquel is one of a family of atypical antipsychotic drugs. Clinical studies conducted by various entities indicate that users of the drug sometimes experience serious and debilitating side effects including, but not limited to, tardive dyskinesia, neuroleptic malignant syndrome (NMS), hyperglycemia, diabetes, orthostatic hypotension, interference with cognitive and motor performance.
- 17. Of all of the atypical antipsychotic drugs, Seroquel is the most heavily sedating thus, if not properly monitored, it predisposes non-ambulatory patients to pneumonia and other respiratory ailments.
- 18. The risk to a Seroquel user experiencing the aforementioned negative side effects is much greater with increases in drug dosage, age and length of time one is exposed to the drug. Misuse or prolonged use of Seroquel can pose special danger to the elderly and pediatric patients.
- 19. Although the revised package insert for Seroquel specifically says, "the safety and effectiveness of Seroquel in pediatric patients have not been established, AstraZeneca has embarked upon an aggressive marketing program targeting physicians treating children". Both children and elderly patients are at increased risk for developing extrapyramidal symptoms ("EPS") which are physical movement disorders that can result in irreversible lifelong illness, including, but not limited to Tardive Dyskinesia.

A. THE USE OF "MEDICAL EDUCATION" AS SALES PROMOTION

20. One method of promoting the use of Seroquel has been to pay physician speakers who have conducted what is known in the industry as "investigator initiated trials" (IIT's").

- 21. IIT's funded by AstraZeneca have been used to promote off-label use of Seroquel for children and adolescents; elderly patients with Alzheimer's/dementia; Parkinson's Disease; conduct disorder in children; refractory depression; sleep deprivation and anxiety.
- 22. AstraZeneca routinely sponsors Continuing Medical Education and other promotional programs focused on the treatment of mood disorders which highlight the effectiveness of Seroquel in comparison to other atypical psychotropic medicines.
- 23. The programs employ the use of medical education networks like: DLN (Distance Learning Network); Psychlink and MedScape. These satellite broadcasts are done live and then rebroadcast the same day and subsequently in taped format.
- 24. AstraZeneca has disregarded the limitations on the use of Seroquel set forth by FDA indications and federal law. AstraZeneca's sales force and the outside physician which it sponsors aggressively promoted the prescription of the drug in ways that have not been shown to be clinically safe, medically necessary or effective.
- 25. AstraZeneca management provides its sales force with sealed invitations to these programs which they, in turn, provide to their customer physicians.
- 26. During 2003, AstraZeneca sponsored a MedScape program on the "Comprehensive Management Of Behavioral Disturbances In Dementia". The target audience was physicians, gerontologists, nurses, pharmacists and other health care professionals treating the elderly. One of the learning objectives of the program was to "delineate the important issues and behavioral management of patients in nursing homes". Another was to "review the features of pharmacologic intervention in nursing home patients". Publication of this program was promoted by the AstraZeneca sales force by use of sealed invitations being provided to physician customers.

- 27. As recently as March 5, 2004, the "Seroquel Team" sent an announcement to various sales forces within the company again announcing a "free internet-based CME/CE activity" entitled "Comprehensive Management of Behavioral Disturbances in Dementia" ("Comprehensive Management"). The program could be accessed on MedScape.
- 28. The sales force receiving the Seroquel Team invitation were warned, "Please note that the enclosed invitation must remain in the enclosed envelope to insure that the program is not associated with any promotional activity. Thank you for helping to supplement MedScape's distribution of this program". The memorandum ended with the salutation "Good Selling".
- 29. The Comprehensive Management program was authored by Martin L. Korn, M.D. and William E. Reichman, M.D., and funded by AstraZeneca. It promoted the use of Seroquel over other atypical psychotropic medicines.
- 30. Despite the risk to patients using Seroquel, AstraZeneca made a marketing decision to aggressively promote its drug to physicians for prescription to "higher functioning patients".

 Particular pressure has been placed on sales persons whose customers include those treating children and the elderly in nursing homes, as well as prisoners in detention facilities.

 Dangerously rapid titration and excessive doses of the drug have also been actively promoted despite inherent dangers.

B. <u>ASTRAZENECA PROMOTES THE OFF LABEL SALES OF SEROQUEL</u> TO ALZHEIMERS PATIENTS

31. On December 22, 2003, the Seroquel Team distributed a memorandum regarding a CME program concerning "the Use of Atypicals in Alzheimer's/Dementia". Seroquel is not FDA indicated for treatment of Alzheimer's/dementia.

- 32. The memorandum touted an internet-based CME case study titled "Optimizing Use of Antipsychotics in Patients With Dementia". This program was authored by Dr. Pierre Tariot and was available by visiting the web site, www.igr.medsite.com.
- 33. Sales teams were warned, "Please note that the enclosed invitation must remain in the enclosed white envelope to insure that the program is not associated with any promotional activity. Thank you for your help in supplementing MedSite's distribution of this program". The memorandum ended with the salutation "Good Selling!"
- 34. On March 16, 2004, a memorandum was distributed from Michelle Hagan, DLN, site coordinator. It was distributed to AstraZeneca's sales representatives re: "Upcoming CME activity". It noted future CME activity sponsored by AstraZeneca to include: 10/19/04 dementia/agitation/Parkinson data and 11/30/04 borderline/special populations/MRDD. On information and belief, these training programs will again focus on the prescription of Seroquel for off-label usage.
- 35. The Omnibus Budget Reconciliation Act of 1987 ("OBRA") called for the promulgation of regulations to guard against unnecessary prescription of psychotropic medication to nursing home residents. 42 C.F.R. §483.25(1)(1) and (2) requires that nursing home residents that receive antipsychotic drugs, like Seroquel, must be diagnosed as having a specific condition documented in the facility's clinical record. Such residents are to receive gradual dose reductions and behavioral interventions unless clinically contraindicated. The condition must be persistent and not the result of a preventable event. The condition must either cause the resident to present a danger to himself or to others or occur in a patient who is experiencing psychotic symptoms, such as hallucinations and delusions.

- 36. OBRA surveyor guidelines state that depression, absent severely psychotic symptoms, anxiety and even agitated behaviors which do not represent a danger to the resident or others and, therefore, are not a justification for prescribing drugs like Seroquel.
- 37. Nursing homes failing to adhere to these guidelines may be considered to be providing unnecessary medications.
- 38. AstraZeneca regularly publicizes effective selling methods in monthly newsletters as what the company describes as "Best Practices". A copy of portions of the June 2002 "Best Practice" describes how AstraZeneca sales representatives might bypass nursing home OBRA regulations in promoting the prescription of Seroquel to persons residing in assisted living accommodations. (Attached hereto as Exhibit "A").
- 39. By definition, persons residing in assisting living accommodations are higher functioning individuals capable of living on their own with minimal help and supervision.
- 40. Despite the high functioning abilities of assisted living residents, The June 2002 newsletter, "Best Practice" reads as follows:

As nursing home care represents sicker patients on increasing 'short term' stays (currently an average of 6-10 months vs. 2-3 years 5 years ago), assisted living plays a much greater role. This is an important consideration since assisted living is not regulated to the same extent as nursing homes. By keeping in mind the distinctive needs of the Long-term Care providers and the challenges they face, it is increasingly clear that Seroquel is the best choice for improving the quality of life in the elderly patients and offers clear advantages in the Long-term Care setting."

- 41. The June 2002 "Best Practice" specifically contradicts FDA indications stating that:
 - "The effectiveness of Seroquel in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials."
- 42. During 2003, AstraZeneca sponsored a program concerning "Central Nervous System Disorders". Physicians invited by closed seal envelope invitations from the AstraZeneca sales

force were advised that after completing the case study review, they would be able to "identify and evaluate patients with dementia by employing a systematic approach and to identify the differences between typical and atypical antipsychotics". Seroquel is not FDA approved for the treatment of dementia or Alzheimer's disease.

- 43. Until May 2004, AstraZeneca's heavy promotion for the prescription of Seroquel to long term health care patients failed to take into any account the relatively rare occurrence of either bipolar II mania or schizophrenia in the elderly.
- 44. Until May 2004, the CME presentations sponsored by AstraZeneca either failed to mention or discredited federal regulatory guidelines concerning the requirement that use of Seroquel in nursing homes, correctional facilities or Veteran's Administration Hospitals require documentation of the condition of the patient, both objectively and quantitatively. The same regulations require exact notation of dosage.
- 45. Following May 13, 2004, AstraZeneca conceded its inappropriate off-label promotion of Seroquel. A management decision was made to have the company's Long Term Care sales force end its off-label promotion of Seroquel in nursing homes. An explanatory internal voice stated the following:

"While the Long Term Sales force has been in place for five years and has generated huge Seroquel Dollar Volume, these representatives had little direction in the past and their discussions with physicians routinely centered on the use of Seroquel in treating agitation sleep and other off-label indications in nursing homes." (emphasis added)

The same voicemail announced the termination of physicians from the Long Term Sales force who were prescribing Seroquel for off-label use.

46. Sally Plumly is a nurse practitioner retained by AstraZeneca sales representatives to advocate the use of Seroquel in treating agitation in those afflicted with Alzheimer's disease.

Following management's May 2004 decision to de-emphasize off-label promotion of Seroquel for Alzheimer patients, Plumley was told to remove all off-label slides from her presentation.

C. OFF-LABEL PRESCRIPTION OF SEROQUEL FOR CHILDREN

47. The 2001 package insert states the following as to Clinical Efficacy:

Examination of population subsets (race, gender and age) did not reveal any differential responsiveness on the basis of race or gender, with an apparently greater effect in patients under the age of 40 compared to those older than 40. The clinical significance of this finding is unknown.

- 48. Dr. Melissa DelBello has been retained by AstraZeneca to help in its promotion of Seroquel to pediatric patients. In calendar year 2003, Dr. DelBello was paid \$134,000 by AstraZeneca to assist in the marketing of Seroquel to pediatric patients. As of March, 2004, she has been paid \$32,000 for 16 programs.
- 49. Dr. DelBello's single study concerns the use of Seroquel in combination with depakote for the treatment of mania in bipolar adolescent children. Dr. DelBello's study was funded by AstraZeneca. The scientific value of the study is questionable for the following reasons: 1) the sample on which the study is based includes only 30 patients; 2) the response rate is much higher than that of a larger study of 191 patients. Dr. DelBellos' study claims an 87% response rate versus 53% in an FDA approved adult study.
- 50. Despite Dr. DelBello's purported findings, the AstraZeneca package insert for Seroquel reads: Pediatric Use "The safety and effectiveness of Seroquel in pediatric patients have not been established."
- 51. The printed materials that accompany Dr. DelBello's presentations feature young children. One is entitled "Treatment of Bipolar Disorder Across the Life Span". These materials de-emphasize the health risks attendant to long term exposure to atypical antipsychotics.
 - 52. The Seroquel package insert specifically warns:

The effectiveness of SEROQUEL in long term use, that is, for more than 6 weeks has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Seroquel for extended periods should periodically re-evaluate the long term usefulness of the drug for the individual patient.

- 53. In addition to paying Dr. DelBello directly, AstraZeneca supports her in other ways.

 AstraZeneca sales representative's "call notes" states that Dr. DelBello is very pleased that

 AstraZeneca is using her husband's catering business to do the off-label Seroquel lunches.
- 54. AstraZeneca management directed the AstraZeneca sales force to make copies of the slides presented by Dr. DelBello at a March 31, 2004 presentation. The slides were to be distributed to all participating physicians
- 55. The presentations made by Dr. DelBello do little to alert the physician/health care provider audience to the possible long term side effects linked to Seroquel use in children, such as tardive dyskenesia, cataracts and neuroleptic malignant syndrome.
- 56. Dr. DelBello makes presentations throughout the United States. A presentation made in Pittsburgh, Pennsylvania was with AstraZeneca's assistance linked to 30 separate satellite locations.
- 57. Dr. DelBello speaks to groups of health care professionals with authority to prescribe or suggest the prescription of Seroquel to children. For example, on March 17, 2003, she made a Seroquel sales promotion at Saint Joseph's Orphanage in Cincinnati, Ohio for which she was paid \$1,500.00.

D. <u>SEROQUEL'S OFF-LABEL PROMOTIONS IN DETENTION</u> FACILITIES AND VETERANS ADMINISTRATION

58. AstraZeneca has also retained the services of Dr. Angela Hegarty, a forensic psychiatrist, from New York. Most recently, she was the key note speaker at the California Department of Corrections Advisory Board meetings. Each of the attendees, including

California Correctional Psychiatrists were paid honoraria, as well as all meeting expenses. At the discussion, Seroquel was touted as a "first line agent for aggressive patients".

- 59. On information and belief, AstraZeneca is also targeting Veteran's Administration Hospital administrators for use of Seroquel.
- 60. AstraZeneca regularly reaches out to governmental employees at the Veteran's Administration and in correctional institutions by offering them honoraria payments between \$500-\$750 so that they might learn more about the "off-label uses of Seroquel".
- 61. In August, 2003, Seroquel set up at least one VA regional advisory board meeting in California. Each VA psychiatrist was to receive a \$750.00 honorarium, plus payment of all expenses to attend. For unknown reasons, this particular meeting was cancelled.

E. OTHER OFF LABEL PROMOTIONS AND PROMOTIONS OF SEROQUEL

- 62. AstraZeneca also encourages future speakers to initiate their own ITT's regarding off-label use of Seroquel. On information and belief, these ITT's do not meet the standards of FDA approved clinical trials. These non-FDA standard trials are then used in company sponsored CME programs focused on such maladies as Parkinson's disease, refractory depression and other mood disorders.
- 63. AstraZeneca retained Dr. Henry A. Nasrallah to do numerous off-label talks and discussions on CME satellite and on-line programs. On information and belief, Dr. Nasrallah's book, "The Patient With Schizophrenia" was written under the sponsorship of AstraZeneca.
- 64. AstraZeneca has shipped approximately 300,000 400,000 copies of these books to its sales force for distribution.
- 65. In 2003, AstraZeneca paid Dr. Nasrallah \$285,000 in return for his presentations to physicians.

- 66. In 2004, Dr. Nasrallah received \$10,000 in grant money for a symposium to be run in the fall of 2004.
- 67. Dr. Nasrallah has asked one AstraZeneca sales representative to pay the fees for his personal advertisement in his local psychiatric society journal.

F. RAPID TITRATION

- 68. Dr. Rimal Bera is another physician retained by AstraZeneca to promote off-label use of Seroquel. Dr. Bera received approximately \$175,000 from AstraZeneca in honoraria for CME lectures in 2003. He has received \$55,000 for 41 presentations in 2004.
- 69. The principal competitive drawback of Seroquel in comparison to its competitors, Zyprexa and Risperdal, is that it requires a relatively slow titration in order for patients to become accustomed to it with minimal negative side effects.

The labeling for Seroquel suggests a titration of four days building from 25mg to 300-400mg a day. A slower rate of titration and target dose is recommended for the elderly because older patients are more likely to experience serious negative side effects.

- 70. Despite the FDA approved warnings, the call notes of two salespersons reveal Dr. Bera recommends a titration schedule of 200mg/day one; 400mg./day two; 600mg./day three. He states that his study showed excellent results and tolerability. Call notes of two salespersons for Dr. Bera described him recommending doses of up to 1200mg. per day.
- 71. Dr. Bera's recommendations are contrary to package insert indications. Under the insert's heading "Information for Patients", there is a warning against Orthostatic Hypotension". It reads, "Patients should be advised of the risk of orthostatic hypotension, especially during the initial 3-5 day period of initial dose titration, and also at times of reinstating treatment or increases in dose."

- 72. At least one AstraZeneca sales person reports that when she recommended Dr. Bera's titration schedule to a clinic using Seroquel, she was told that "two patients coded requiring emergency resuscitation. On information and belief, a required Adverse Event Report was never filed in connection with this off-label usage.
- 73. On May 20, 2004, Dr. Bera made a slide presentation in Chico, California promoting the use of atypical antipsychotic drugs. One slide in his presentation discussed use of these drugs in children for "conduct disorders".
- 74. Another slide noted that "70% of atypical antipsychotics are being prescribed outside of Schizophrenic/Schizoaffective Disorders". The same slide described various off-label uses of antipsychotics to include drug abuse, anorexia nervosa, obsessive-compulsive disorder, stuttering and other ailments not usually associated with treatment by atypical antipsychotics.
- 75. Dr. Rajiv Tandon is also a frequent AstraZeneca speaker on off-label usage. Dr. Tandon received \$94,250 in 2003 in payments from AstraZeneca for his presentations. Contrary to FDA guidelines, Dr. Tandon recommends starting patients at 200mg on day one, increasing to 200mg/ day to 600mg, a day by day 3.
- 76. Dr. Tandon regularly advocates doses of Seroquel of up to 1200mg./day. Dr. Tandon's recommendations significantly exceed all FDA approved indications.
 - 77. FDA approved indications included in the Seroquel package insert state:

"Seroquel should generally be administered with an initial dose of 25mg. b.i.d. with increases in increments of 25-50mg. b.i.d. or t.i.d. on the second and third day, as tolerated".

The warning also notes that although some studies have shown doses in the range of 400-500mg/day appear needed, doses above 300mg/day have not proven to be more efficacious than doses above 300mg/day. It specifically states that the safety of doses above 800mg/day has not been evaluated in clinical trials.

- 78. The same FDA approved indication states "the special" consideration should be given to a slower rate of dose titration and a lower target dose in the elderly, and in patients who are debilitated or who have a predisposition to hypotensive reactions.
- 79. The Seroquel package insert also warns that the possibility of a suicide attempt is inherent in schizophrenia and close supervision of high risk patients should accompany drug therapy.

G. USE OF QUESTIONABLE STUDIES TO SELL SEROQUEL

- 80. "Call Notes" are written comments made by salespeople following sales contacts with physicians and other health care providers who might be in a position to order AstraZeneca drugs. They are used by members of the sales force to keep each other informed. Recent Call Notes indicate improper liberties taken in clinical studies used in sales promotion.
- 81. One call note describes questionable open label studies (patient and health care provider is informed that he is receiving the active drug)

"Saw at UCare... Everything looks good. Said should pass IRB (Investigation Review Board) no problems. It will be open labeled and if patient fails will be eliminated from study. Dr. Potkin's study not IRB approved due to double blind nature".

- 82. AstraZeneca sales representatives routinely initiate and send Professional Information Requests ("PIRs") whereby physicians receive off-label information on Seroquel. Much of the data contained in these PIRs comes from the ITT's paid for by AstraZeneca.
- 83. AstraZeneca regularly makes use of Advisory Board Meetings to promote the offlabel use of Seroquel. Physicians paid as "consultants" receive honorariums to attend meetings regarding the off-label use of the drug. Although the purported purpose of the meetings is to receive feedback from the physicians concerning off-label use, they are actually used to

incentivize the physicians use of Seroquel for off-label use to the exclusion of less expensive and medically dangerous alternatives.

IV. OVERLY AGGRESSIVE PROMOTION OF SEROQUEL TO PRIMARY CARE PHYSICIANS

- 84. Seroquel's FDA approved use is limited to the short term treatment of acute episodes of schizophrenia and Bipolar I disorder.
- 85. Patients suffering from either schizophrenia or Bipolar I disorder are most frequently and most appropriately under the care of psychiatrists, and not primary care physicians. Both illnesses represent acute conditions wherein the patient is disoriented from reality, often suffering from hallucinations and severe delusions.
- 86. Despite these limitations as to which doctors are best trained and most experienced in the treatment of those suffering from Bipolar I and schizophrenia, AstraZeneca is actively encouraging primary care physicians to prescribe Seroquel to patients suffering from "bipolar type and schizophrenic type symptoms".
- 87. AstraZeneca sales people are instructed by their managers to overcome resistance to prescribing Seroquel by primary care physicians with such tactics as telling those doctors: 1) to consider how much time it might take their patients before they are able to obtain an appointment with a psychiatrist or; 2) that there is an objection to prescribe Seroquel for those patients who say, "doctor, I'm not crazy".
- 88. On August 3, 2004, AstraZeneca announced a promotion of a company-wide sales effort to push Seroquel to primary care physicians through its Primary Physicians sales force.
- 89. On August 12, 2004, various AstraZeneca sales people were contacted by voice mail, advising them of the company-wide effort to promote sales of Seroquel to primary care physicians because this was to be the "future of Seroquel".

90. AstraZeneca's aggressive sales promotion of Seroquel to primary care physicians is needlessly exposing the patients of these physicians to the adverse side effects of this atypical antipsychotic drug.

V. ASTRAZENECA CONCEDES THE IMPROPRIETY OF ITS OFF LABEL PROMOTIONS

- 91. Following the March 25, 2004 announcement that the Eli Lilly Pharmaceutical Company was under federal investigation for its marketing of its atypical antipsychotic drug, Zyprexa, AstraZeneca began to de-emphasize its off-label marketing of Seroquel.
- 92. On May 17, 2004, members of the AstraZeneca Seroquel sales force were instructed to discontinue their current physician grant process <u>until later in the year</u>. The sales people were advised "The Company Wants To Win the Right Way". To that time it had been AstraZeneca's practice to provide cash grants to physicians willing to conduct favorable studies promoting Seroquel.
- 93. The United States government sanctioned AstraZeneca in 2003 for its illegal promotion of its drug, Zolodex, through the use of "free samples" as "kickbacks" to physicians. As part of its settlement, salespeople were to be trained in their ethical obligation. Rather than insisting upon a strict training regimen, salespeople need only assert that they have read the required compliance materials

VIOLATION OF THE FALSE CLAIMS ACT, 31 U.S.C. §3729

- 94. Relator repeats and realleges paragraphs 1-93 of this Fifth Amended Complaint.
- 95. From at least sometime in 2002 and continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, conspired with various physicians to defraud the United States government by causing false or fraudulent claims to be paid or approved by the government in violation of 31 U.S.C.

§3729(a)(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for persons for whom either initial or sustained us of the drug is inappropriate or unsafe.

96. From at least March, 2003 to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, conspired with doctors to cause to be presented and are still presenting or causing to present to various state and federally funded Medicaid health care programs false or fraudulent claims for payment in violation of 31 U.S.C. §3729(a)(3).

97. The United States, its fiscal intermediaries and state Medicaid programs, were unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result have paid and continue to pay Medicare, Medicaid and CHAMPUS reimbursement that they would not otherwise have paid.

98. The United States and the state Medicaid programs have been damaged by the payment of false or fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

- a. That by reason of the aforementioned violations of the False Claims Act this Court enter judgment in Plaintiff's favor and against AstraZeneca in an amount equal to three (3) times the amount of damages that the United States has sustained because of AstraZeneca's and co-conspirators' actions, plus a civil penalty of not less than \$5,000 nor more than \$10,000 for each violation of 31 U.S.C. §3729;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act and/or any other applicable provision of the law;
- c. That Relator be awarded all costs and expenses of this action, including attorneys' fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT II RETALIATION IN VIOLATION OF 31 U.S.C. §3730(H)

- 99. Relator James Wetta had been a longtime sales representative, in good standing for AstraZeneca.
- 100. AstraZeneca management sought to increase its sales of Seroquel by having its sales representatives recommend that the drug be used in ways not approved by the FDA and in disregard of possible consequences resulting from such use.
- 101. Specifically, James Wetta was instructed by his mangers at AstraZeneca to promote the use of Seroquel to child and adolescent psychiatrists, primary care physicians, and to elderly patients suffering from age related dementia despite his protests against doing so.
- 102. James Wetta was also instructed to persuade physicians to experiment with titration and dosing schedules well beyond what the FDA considers safe, again despite his protests against doing so.
- 103. Uncomfortable and upset with the directions he was receiving, James Wetta repeatedly complained to AstraZeneca management about inappropriate marketing activities.
- 104. Prior to resisting AstraZeneca's off-label marketing demands, James Wetta had received uniformly positive ratings in his evaluations.
- 105. As Mr. Wetta persisted in making known his reservations regarding off-label marketing of Seroquel known to sales management, his ratings were downgraded and he was criticized for his refusal to participate in what he considered to be the unethical off-label promotion of Seroquel for non-FDA approved uses, his health began to suffer.

- 106. On or about June 15, 2005, James Wetta required treatment for anxiety, insomnia and depression. He was advised by his psychiatrist to discontinue working. He has continued to treat with this same psychiatrist
- 107. On his doctor's advice, on or about June 15, 2005, James Wetta declared his short term disability.
- 108. Immediately following James Wetta's departure for disability leave, he found out that his managers at AstraZeneca set up a teleconference for early August during which a board certified child, adolescent and adult psychiatrist was to present a speech promoting the use of Seroquel.
- 109. The target audience for the presentation was child and adolescent psychiatrists primarily treating children in their practices.
- 110. Specifically, several child and adolescent psychiatrists from James Wetta's sales territory participated in the conference, including at least three of whom were county employees whose practices revolve mainly around the treatment of children.
- 111. The actions taken by James Wetta's manager, and by AstraZeneca's uppermanagement, made it impossible for him to return to work and market Seroquel the way that AstraZeneca and management required.
- 112. Soon after making his declaration of disability, Mr. Wetta began to receive phone calls and letters threatening him with termination.
- 113. Despite being advised of Mr. Wetta's disability by his psychiatrist, AstraZeneca terminated his salary as of September 30, 2005.

- 114. Despite Mr. Wetta's reports of regular physician visits and contrary to company policy, AstraZeneca denied his request for extended leave without seeking a second medical/legal opinion.
 - 115. As of December 14, 2005, his employment with AstraZeneca was terminated.
- 116. Section 3720(h) precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, 31 U.S.C. §3729.
 - 117. James Wetta's constructive discharge was in violation of 31 U.S.C. §3730(h).
- 118. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 119. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of 31 U.S.C. §3730(h).

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to 31 U.S.C. §3730(h) including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT III</u> <u>VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT, CAL. GOV. CODE §12651</u>

- 120. Relator repeats and realleges paragraphs 1-119 of this Fifth Amended Complaint.
- 121. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the state of California by using false or fraudulent claims to be paid or approved by the state of California in violation of CAL. GOV. CODE §12651(a)(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 122. California's state Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 123. The California State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the California False Claims Act that this Court enter judgment in Plaintiff's favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that California has sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil penalty of not more than \$10,000 for each violation of CAL. GOV. CODE §12651(a)(3);
- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to CAL. GOV. CODE §12652(g)(2) and/or any other applicable provision of law;

- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

<u>COUNT IV</u> <u>RETALIATION IN VIOLATION OF CAL. GOV. CODE. § 12653</u>

- 124. Relator repeats and realleges paragraphs 1-123 of this Fifth Amended Complaint.
- 125. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.
- 126. Section12653 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, CAL. GOV. CODE. § 12652.
- 127. James Wetta's constructive discharge was in violation of CAL. GOV. CODE. § 12653.
- 128. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 129. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of CAL. GOV. CODE. § 12653.

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to CAL. GOV. CODE. § 12650-12655 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT V</u> <u>VIOLATION OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT, DEL.</u> <u>CODE ANN, TIT. 6 §1201</u>

- 130. Relator repeats and realleges paragraphs 1-129 of this Fifth Amended Complaint.
- 131. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the state of Delaware by using false or fraudulent claims to be paid or approved by the state of Delaware in violation of DEL. CODE ANN. TIT. 6, §1201(a)(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 133. The Delaware State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

a. that by reason of the aforementioned violations of the Delaware

False Claims and Reporting Act that this Court enter judgment in Plaintiff's favor and against

AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that Delaware has sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of DEL. CODE ANN. TIT. 6, §1201(a)(3);

- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to DEL. CODE ANN. tit. 6, §1205(a)and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT VI RETALIATION IN VIOLATION OF DEL. CODE ANN. TIT. 6 § 1208

- 134. Relator repeats and realleges paragraphs 1-133 of this Fifth Amended Complaint.
- 135. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.
- 136. Section 1208 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, DEL. CODE ANN. TIT. 6 § 1201.
- 137. James Wetta's constructive discharge was in violation of DEL. CODE ANN. TIT.6 § 1208.
- 138. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and

monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.

139. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of DEL. CODE ANN. TIT. 6 § 1208

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to DEL. CODE ANN. TIT. 6 § 1201-1209 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

COUNT VII VIOLATION OF D.C. CODE ANN. §§2-308.13-.15

- 140. Relator repeats and realleges paragraphs 1-139 of this Fifth Amended Complaint.
- disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the District of Columbia by using false or fraudulent claims to be paid or approved by the District of Columbia in violation of D.C. CODE ANN. §2-308.14(a)(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 142. The District of Columbia's Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-

conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.

143. The District of Columbia's Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the District of Columbia's false claim provisions that this Court enter judgment in Plaintiff's favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that the District of Columbia has sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of D.C. CODE ANN. §2-308.14(a)(3);
- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to D.C. CODE ANN. §2-308.15(f)(1) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT VIII RETALIATION IN VIOLATION OF D.C. CODE § 2-308.16

- 144. Relator repeats and realleges paragraphs 1-143 of this Fifth Amended Complaint.
- 145. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.

- 146. Section 2-308.16 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, D.C. CODE § 2-308.13-15.
 - 147. James Wetta's constructive discharge was in violation of D.C. CODE § 2-308.16.
- 148. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 149. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of D.C. CODE § 2-308.16.

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to D.C. CODE § 2-308.13-21 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT IX</u> <u>VIOLATION OF THE FLORIDA FALSE CLAIMS ACT, FLA. STAT. ANN. §68.081-.090</u>

- 150. Relator repeats and realleges paragraphs 1-149 of this Fifth Amended Complaint.
- 151. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired

with various physicians to defraud the state of Florida by using false or fraudulent claims to be paid or approved by the state of Florida in violation of FLA. STAT. ANN. §68.082(2)(a)(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.

- 152. Florida's state Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 153. The Florida State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the Florida False Claims Act that this Court enter judgment in Plaintiff's favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that Florida has sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of FLA. STAT. ANN. §68.082(2)(a)(3);
- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to FLA. STAT. ANN. §68.085(1)-(2) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT X RETALIATION IN VIOLATION OF FLA. STAT, ANN. § 68.088

- 154. Relator repeats and realleges paragraphs 1-153 of this Fifth Amended Complaint.
- 155. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.
- 156. Section § 68.088 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, FLA. STAT. ANN. § 68.081-90.
- 157. James Wetta's constructive discharge was in violation of FLA. STAT. ANN. § 68.088.
- 158. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 159. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of FLA. STAT. ANN. § 68.088.

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to FLA. STAT. ANN. § 68.081-089 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back

pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

COUNT XI VIOLATION OF HAW. REV. STAT. §§661-21 to 661-29

- 160. Relator repeats and realleges paragraphs 1-159 of this Fifth Amended Complaint.
- 161. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the state of Hawaii by using false or fraudulent claims to be paid or approved by the state of Hawaii in violation of HAW. REV. STAT. §661-21(a)(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 162. Hawaii's state Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 163. The Hawaii State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

a. that by reason of the aforementioned violations of Hawaii's false claim provisions that this Court enter judgment in Plaintiff's favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that Hawaii has sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil

penalty of not less than \$5,000 and not more than \$10,000 for each violation of HAW. REV. STAT. §661-21(a)(3);

- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to HAW. REV. STAT. §661-27(a) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this
 Court deems just and proper.

<u>COUNT XII</u> <u>VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION</u> <u>ACT, 740 ILL. COMP. STAT. 175/1-8</u>

- 164. Relator repeats and realleges paragraphs 1-163 of this Fifth Amended Complaint.
- disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the state of Illinois by using false or fraudulent claims to be paid or approved by the state of Illinois in violation of 740 ILL. COMP. STAT. 175/3(a)(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 166. Illinois' state Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 167. The Illinois Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. that by reason of the aforementioned violations of the Illinois
 Whistleblower Reward and Protection Act that this Court enter judgment in Plaintiff's favor and
 against AstraZeneca in an amount equal to three times the amount of damages that Illinois has
 sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil penalty of not
 less than \$5,000 and not more than \$10,000 for each violation of 740 ILL. COMP. STAT. 175/
 3(a)(3);
- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to 740 ILL. COMP. STAT. 175/4(d)(1) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XIII RETALIATION IN VIOLATION OF 740 ILL. COMP. STAT. 175/4

- 168. Relator repeats and realleges paragraphs 1-167 of this Fifth Amended Complaint.
- 169. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.
- 170. Section 175/4 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, 740 ILL. COMP. STAT. 175/1-8.
- 171. James Wetta's constructive discharge was in violation of 740 ILL. COMP. STAT. 175/4.

- 172. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 173. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of 740 ILL. COMP. STAT. 175/4.

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to 740 ILL. COMP. STAT. 175/1-175/8 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT XIV</u> <u>VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS</u> <u>INTEGRITY LAW, LA, REV. STAT. ANN. §§46:437.1–440.3</u>

- 174. Relator repeats and realleges paragraphs 1-173 of this Fifth Amended Complaint.
- 175. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the state of Louisiana by using false or fraudulent claims to be paid or approved by the state of Louisiana in violation of LA. REV. STAT. ANN. §46:438.3(C) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.

- 176. Louisiana's state Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 177. The Louisiana State Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. that by reason of the aforementioned violations of the Louisiana Medical Assistance Programs Integrity Law that this Court enter judgment in Plaintiff's favor and against AstraZeneca in an amount not to exceed three times the amount of damages that Louisiana has sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil penalty of not more than \$10,000 for each violation of LA. REV. STAT. ANN. §46:438.3(C);
- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to LA. REV. STAT. ANN. §46:438.4(A) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XV RETALIATION IN VIOLATION OF LA. REV. STAT. ANN. §46:439.1

- 178. Relator repeats and realleges paragraphs 1-177 of this Fifth Amended Complaint.
- 179. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.

- 180. Section §46:439.1 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, LA. REV. STAT. ANN. §§46:437.1-440.3.
- 181. James Wetta's constructive discharge was in violation of LA. REV. STAT. ANN. §46:439.1.
- 182. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 183. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of LA. REV. STAT. ANN. §46:439.1.

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to LA. REV. STAT. ANN. §§46:437.1–440.3 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT XVI</u> <u>VIOLATION OF MASS, GEN. LAWS. CH. 12, §5A-50</u>

184. Relator repeats and realleges paragraphs 1-183 of this Fifth Amended Complaint.

- disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the Commonwealth of Massachusetts by using false or fraudulent claims to be paid or approved by the Commonwealth of Massachusetts in violation of MASS. GEN. LAWS. CH. 12, §5B(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 186. Massachusetts' Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 187. The Massachusetts Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. that by reason of the aforementioned violations of Massachusetts' false claim provisions that this Court enter judgment in Plaintiff's favor and against AstraZeneca in an amount equal to three times the amount of damages, including consequential damages that the Commonwealth of Massachusetts has sustained because of AstraZeneca's and its coconspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of MASS. GEN. LAWS. CH. 12, §5B(3);
- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to MASS. GEN. LAWS. CH. 12, §5F(1)-(3) and/or any other applicable provision of law;

- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XVII RETALIATION IN VIOLATION OF MASS. GEN. LAWS. CH. 12, §5J

- 188. Relator repeats and realleges paragraphs 1-187 of this Fifth Amended Complaint.
- 189. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.
- 190. Section §5J precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, MASS. GEN. LAWS. CH. 12, §5A-5O.
- 191. James Wetta's constructive discharge was in violation of MASS. GEN. LAWS. CH. 12, §5J.
- 192. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 193. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of MASS. GEN. LAWS. CH. 12, §5J.

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to MASS. GEN. LAWS. CH. 12, §5A-5O including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT XVIII</u> <u>VIOLATION OF NEV. REV. STAT. § 357.010–.250</u>

- 194. Relator repeats and realleges paragraphs 1-193 of this Fifth Amended Complaint.
- 195. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the state of Nevada by using false or fraudulent claims to be paid or approved by the state of Nevada in violation of NEV. REV. STAT. § 357.014(1)(c) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 196. Nevada's state Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 197. The Nevada State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

a. that by reason of the aforementioned violations of Nevada's false claim provisions that this Court enter judgment in Plaintiff's favor and against AstraZeneca in an

amount equal to three times the amount of damages that Nevada has sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of NEV. REV. STAT. § 357.014(1)(c);

- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to NEV. REV. STAT. § 357.210(1) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XIX RETALIATION IN VIOLATION OF NEV. REV. STAT. § 357.240

- 198. Relator repeats and realleges paragraphs 1-197 of this Fifth Amended Complaint.
- 199. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.
- 200. Section § 357.240 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, NEV. REV. STAT. §§ 357.010–.250.
- 201. James Wetta's constructive discharge was in violation of NEV. REV. STAT. § 357.240.
- 202. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being

constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.

203. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of .

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to NEV. REV. STAT. § 357.010–250 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT XX</u> <u>VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT, TENN. CODE</u> <u>ANN. §§71-5-181 to 185</u>

- 204. Relator repeats and realleges paragraphs 1-203 of this Fifth Amended Complaint.
- 205. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the state of Tennessee by using false or fraudulent claims to be paid or approved by the state of Tennessee in violation of TENN. CODE ANN. §71-5-182(a)(1)(C) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 206. Tennessee's state Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.

207. The Tennessee State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the Tennessee Medicaid False Claims Act that this Court enter judgment in Plaintiff's favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that Tennessee has sustained because of AstraZeneca's and its coconspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of TENN. CODE ANN. §71-5-182(a)(1)(C);
- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to TENN. CODE ANN. §71-5-183(c)(1) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXI RETALIATION IN VIOLATION OF TENN. CODE ANN. §71-5-183

- 208. Relator repeats and realleges paragraphs 1-207 of this Fifth Amended Complaint.
- 209. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.
- 210. Section §71-5-183 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, TENN. CODE ANN. §§71-5-181 to 185.

- 211. James Wetta's constructive discharge was in violation of TENN. CODE ANN. §71-5-183.
- 212. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 213. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of TENN. CODE ANN. §71-5-183.

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to TENN. CODE ANN. §§71-5-181 TO -185 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT XXII</u> <u>VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION STATUTE, TEX.</u> <u>HUM. RES. CODE ANN. 36.001-.132</u>

- 214. Relator repeats and realleges paragraphs 1-213 of this Fifth Amended Complaint.
- 215. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the state of Texas by using false or fraudulent claims to be paid or approved by the state of Texas in violation of TEX. HUM. RES. CODE ANN.

§36.002(8) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.

- 216. Texas' state Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 217. The Texas State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the Texas

 Medicaid Fraud Prevention Statute that this Court enter judgment in Plaintiff's favor and against
- b. AstraZeneca in an amount equal to two times the amount of damages that Texas has sustained because of AstraZeneca's and its co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 for each violation of TEX. HUM. RES. CODE ANN. §36.002(8) that results in injury to an elderly person, a disabled person, or a person younger than 18 years of age, or not less than \$1,000 and not more than \$10,000 for each violation of TEX. HUM. RES. CODE ANN. §36.002(8) that does not result in injury to a person;
- c. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to TEX. HUM. RES. CODE ANN. §36.110 and/or any other applicable provision of law;
- d. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

e. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXIII RETALIATION IN VIOLATION OF TEX. HUM. RES. CODE ANN. § 36.115

- 218. Relator repeats and realleges paragraphs 1-217 of this Fifth Amended Complaint.
- 219. Relator specifically incorporates herein by reference the averments set forth in Paragraphs 99-115.
- 220. Section § 36.115 precludes discharge, demotion or retaliation against employees who investigate, provide testimony or assistance in any action filed or to be filed under the False Claims Act, TEX. HUM. RES. CODE ANN. §§ 36.001-.132.
- 221. James Wetta's constructive discharge was in violation of TEX. HUM. RES. CODE ANN. § 36.115.
- 222. As a direct and proximate result of the retaliation, harassment, threats and constructive discharge by the Defendant, James Wetta has suffered and incurred and is suffering and incurring substantial loss of past and future earnings, compensation and other benefits and monies; harm and damage to Wetta's professional reputation and credibility by being constructive and wrongfully discharged in violation of public policy with the false implication and statements of employees, perspective employers and others in the community that Wetta resigned for reasons unrelated to the aforementioned threats and harassment.
- 223. Defendant's conduct was malicious, fraudulent and oppressive and in violation of public policy and in violation of TEX. HUM. RES. CODE ANN. § 36.115.

WHEREFORE, James Wetta requests that judgment be entered against Defendant in his favor and that he be awarded any and all relief pursuant to TEX. HUM. RES. CODE ANN. 36.001-.132 including, but not limited to: (a) Two times the amount of back pay; (b) Interest on

back pay; (c) Any and all other compensatory and special damages; (d) All litigation costs and reasonable attorney's fees; (e) Punitive damages; and (f) Any and such further relief that this Court deems appropriate.

<u>COUNT XXIV</u> <u>VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT, VA. CODE</u> ANN. 8.01-216.1 – 216.19

- 224. Relator repeats and realleges paragraphs 1-223 of this Fifth Amended Complaint.
- 225. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with various physicians to defraud the Commonwealth of Virginia by using false or fraudulent claims to be paid or approved by the Commonwealth of Virginia in violation of VA. CODE ANN. 8.01-216.3(A)(3) when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 226. Virginia's Medicaid program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 227. The Virginia Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against AstraZeneca as follows:

a. that by reason of the aforementioned violations of the Virginia

Fraud Against Taxpayers Act that this Court enter judgment in Plaintiff's favor and against

AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that the Commonwealth of Virginia has sustained because of AstraZeneca's

and its co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of VA. CODE ANN. 8.01-216.3(A)(3);

- b. that Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to VA. CODE ANN. § 8.01–216.7(A) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXV

<u>VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT, GA.</u> <u>CODE ANN. § 49-4-168 – 49-4-168.6</u>

- 228. Relator repeats and realleges paragraphs 1-227 of this Fifth Amended Complaint.
- 229. From at least spring, 2003 continuing to the present, AstraZeneca, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of Georgia by causing false or fraudulent claims to be paid or approved by the state of Georgia in violation of GA. CODE ANN. § 49-4-168.1 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 230. Georgia's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-

conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.

231. The Georgia State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the Georgia False Medicaid Claims Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that Georgia has sustained because of AstraZeneca's and the coconspirators' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of GA. CODE ANN. § 49-4-168.1;
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to GA. CODE ANN. § 49-4-168.2(i) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXVI

<u>VIOLATION OF THE INDIANA STATE FALSE CLAIMS AND WHISTLEBLOWERS</u> <u>PROTECTION ACT, IND. CODE ANN. § 5-11-5.5-1 - 5-11-5.5-18</u>

232. Relator repeats and realleges paragraphs 1-231 of this Fifth Amended Complaint.

- 233. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of Indiana by causing false or fraudulent claims to be paid or approved by the state of Indiana in violation of IND. CODE ANN. § 5-11-5.5-2 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 234. Indiana's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's coconspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 235. The Indiana State Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. that by reason of the aforementioned violations of the Indiana State False Claims and Whistleblower Protection Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that Indiana has sustained because of AstraZeneca's and the coconspirators' actions, plus a civil penalty of not less than \$5,000 each violation of IND. CODE ANN. § 5-11-5.5-2;
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to IND. CODE ANN. § 5-11-5.5-6 and/or any other applicable provision of law;

- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXVII

<u>VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT, MICH. COMP</u> LAWS § 400.601- 400.613

- 236. Relator repeats and realleges paragraphs 1-235 of this Fifth Amended Complaint.
- 237. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of Michigan by causing false or fraudulent claims to be paid or approved by the state of Michigan in violation of MICH. COMP LAWS § 400.603, 606 and 607 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 238. Michigan's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's coconspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 239. The Michigan State Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. that by reason of the aforementioned violations of the Michigan State Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to three times the amount of damages that Michigan has sustained because of AstraZeneca's and the co-conspirators' actions, plus a civil penalty equal to the full amount AstraZeneca unjustly received as a result of its unlawful conduct for violating MICH. COMP LAWS § 400.603, 606 and 607;
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to MICH. COMP LAWS § 400.610a and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXVIII

<u>VIOLATION OF THE MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. § 17-8-401 – 17-8-412</u>

- 240. Relator repeats and realleges paragraphs 1-239 of this Fifth AmendedComplaint.
- 241. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of Montana by causing false or fraudulent claims to be paid or approved by the state of Montana in violation of MONT. CODE

ANN. § 17-8-403 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.

- 242. Montana's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 243. The Montana State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the Montana False Claims Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that Montana has sustained because of AstraZeneca's and the co-conspirators' actions, plus a civil penalty of not more than \$10,000 for each violation of MONT. CODE ANN. § 17-8-403.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to MONT. CODE ANN. § 17-8-410 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXIX

<u>VIOLATION OF THE NEW HAMPSHIRE FRAUD AND FALSE CLAIMS ACT, N.H.</u> <u>REV. STAT. ANN. § 167:58 - 167:61-b</u>

- 244. Relator repeats and realleges paragraphs 1-243 of this Fifth Amended Complaint.
- 245. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of New Hampshire by causing false or fraudulent claims to be paid or approved by the state of New Hampshire in violation of N.H. REV. STAT. ANN. § 167:61-b when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 246. New Hampshire's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's coconspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 247. The New Hampshire State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against AstraZeneca as follows:

a. that by reason of the aforementioned violations of the New

Hampshire Fraud and False Claims Act that this Court enter judgment in Plaintiffs' favor and
against AstraZeneca in an amount equal to not less than two times and not more than three times
the amount of damages that New Hampshire has sustained because of AstraZeneca's and the co-

conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of N.H. REV. STAT. ANN. § 167:61-b.

- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to N.H. REV. STAT. ANN. § 167:61-e and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXX

<u>VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT, N.M. STAT.</u> ANN. § 27-14-1 – 27-<u>14-15</u>

- 248. Relator repeats and realleges paragraphs 1-247 of this Fifth Amended Complaint.
- 249. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of New Mexico by causing false or fraudulent claims to be paid or approved by the state of New Mexico in violation of N.M. STAT. ANN. § 27-14-4 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 250. New Mexico's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-

conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.

251. The New Mexico State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the New Mexico Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to three times the amount of damages that New Mexico has sustained because of AstraZeneca's and the co-conspirators' actions for violation of N.M. STAT. ANN. § 27-14-4.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to N.M. STAT. ANN. § 27-14-9 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXXI

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT, N.Y. STATE FIN. LAW § 187-194

- 252. Relator repeats and realleges paragraphs 1-251 of this Fifth Amended Complaint.
- 253. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of New York by causing false or

fraudulent claims to be paid or approved by the state of New York in violation of N.Y. STATE FIN. LAW § 189 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.

- 254. New York's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's coconspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 255. The New York State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against AstraZeneca as follows:

- a. that by reason of the aforementioned violations of the New York False Claims Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that New York has sustained because of AstraZeneca's and the co-conspirators' actions, plus a civil penalty of not less than \$6,000 and not more than \$12,000 for each violation of for violation of N.Y. STATE FIN. LAW § 189.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to N.Y. STATE FIN. LAW § 190(6) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXXII

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT N.J. STAT. § 2A:32C-1 -17

- 256. Relator repeats and realleges paragraphs 1-255 of this Fifth Amended Complaint.
- 257. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of New Jersey by causing false or fraudulent claims to be paid or approved by the state of New Jersey in violation of N.J. STAT. § 2A:32C-3 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 258. New Jersey's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 259. The New Jersey's State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against AstraZeneca as follows:

a. that by reason of the aforementioned violations of the New Jersey False Claims Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that New Mexico has sustained because of AstraZeneca's and the co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of for violation of N.J. STAT. § 2A:32C-3.

- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to N.J. STAT. § 2A:32C-7 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXXIII

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT 63 OKL. ST. § 5053-5053.7

- 260. Relator repeats and realleges paragraphs 1-259 of this Fifth Amended Complaint.
- 261. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of Oklahoma by causing false or fraudulent claims to be paid or approved by the state of Oklahoma in violation of 63 Okl. St. § 5053.1 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 262. Oklahoma's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's coconspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 263. The Oklahoma's State Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. that by reason of the aforementioned violations of the Oklahoma Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to three times the amount of damages that Oklahoma has sustained because of AstraZeneca's and the co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000, if not already imposed by the Federal False Claims Act for the same or prior action, for each violation of for violation of 63 Okl. St. § 5053.1.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to 63 Okl. St. § 5053.1.4 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXXIV

<u>VIOLATION OF RHODE ISLAND'S STATE FALSE CLAIMS ACT R.I. GEN. LAWS § 9-1.1-1 - 9-1.1-8</u>

- 264. Relator repeats and realleges paragraphs 1-263 of this Fifth Amended Complaint.
- 265. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of Rhode Island by causing false or fraudulent claims to be paid or approved by the state of Rhode Island in violation of R.I. Gen. Laws § 9-1.1-3 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.

- 266. Rhode Island's State Medicaid Program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay Medicaid reimbursement that they would not otherwise have paid.
- 267. The Rhode Island's State Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. that by reason of the aforementioned violations of Rhode Island's Sate False Claims Act that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to three times the amount of damages that Rhode Island has sustained because of AstraZeneca's and the co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000, for each violation of for violation of R.I. Gen. Laws § 9-1.1-3.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-4(d) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

COUNT XXXV

<u>VIOLATION OF WIS, STAT. § 20.931 FOR FALSE CLAIMS FOR MEDICAL ASSISTANCE</u>

268. Relator repeats and realleges paragraphs 1-267 of this Fifth Amended Complaint.

- 269. From at least spring, 2003 continuing to the present, AstraZeneca in reckless disregard or deliberate ignorance of the truth or falsity of the information involved conspired with physicians and pharmacies to defraud the state of Wisconsin by causing false or fraudulent claims to be paid or approved by the state of Wisconsin in violation of Wis. Stat. § 20.931 when they promoted the use of Seroquel for medically unnecessary and unsafe usage for person for whom either initial or sustained use of the drug is inappropriate or unsafe.
- 270. Wisconsin's state medical assistance program was unaware of AstraZeneca's conspiracies or the falsity of the records, statements and claims made by AstraZeneca's co-conspirators and as a result thereby have paid and continue to pay medical assistance reimbursement that they would not otherwise have paid.
- 271. The Wisconsin's state medical assistance program has been damaged by the payment of false and fraudulent claims.

- a. that by reason of the aforementioned violations of Wis. Stat. § 20.931 that this Court enter judgment in Plaintiffs' favor and against AstraZeneca in an amount equal to not less than two times and not more than three times the amount of damages that Wisconsin has sustained because of AstraZeneca's and the co-conspirators' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000, for each violation of for violation of Wis. Stat. § 20.931.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Respectfully submitted,

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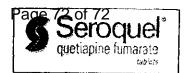


Exhibit A

Jim Hayes and Linda Scott attended a local NAMI meeting.

Key topics of discussion included schizophrenic patients' and the side effects of their medications and the onset of symptoms. Several patients reported that they would not tell a physician about a side effect if they could live with it especially if they had been switched on their medications recently. These patients said that the adjustment to a different medication is difficult on them and their families. Many patients also said that they could tell when symptoms were about to start. They try to warn family members about the symptoms and try to alter their thoughts so that they do not experience severe symptoms such as paranoia. Another area of discussion centered on the need for non-insured patients. The needs and concerns voiced by these patients are strong reminders of what we have to offer with SEROQUEL as well as the added value programs provided by AZ!

Angela Norton has become an active member of the local Alzheimer's Association. This has provided an alternate avenue to interact with key providers in LTC. She has also recently participated in several LTC preceptorships, which have been very insightful to the constant changes in this unique market. As nursing home care represents sicker patients on increasing "short term" stays (currently an average of 6-10 months vs. 2-3 years 5 years ago), assisted living plays a much greater role. This is an important consideration since assisted living is not regulated to the same extent as nursing homes. By keeping in mind the distinctive needs of the LTC providers and the challenges they face, it is increasingly clear that SEROQUEL is the best choice for improving the quality of life in the elderly patients and offers clear advantages in the LTC setting.

